Saint Louis University Institutional Review Board

Additional Criteria for Investigational Drugs

*Check if “Yes” or “N/A.”*

*This worksheet is intended to provide support for individuals in determining how research activity should be regulated. This worksheet is not meant to be retained.*

|  |  |  |
| --- | --- | --- |
| **1 - Drug Applicability** | | |
|  | The research activity involves the following: (Check all that apply)  *Note: If “Yes” for either or both, then complete the remainder of the form. If “No” for both, then FDA regulations do not apply.*  Data regarding subjects or controls submitted to or held for review by the FDA. [[1]](#endnote-1)  Any use of a drug[[2]](#endnote-2) other than a marketed drug used during the course of medical practice (including off-label clinical use). [[3]](#endnote-3) | |
| **2 - IND Requirements** (MUST check at least one) | | |
|  | The drug has a valid IND. (Complete Sections 3 and 4) | |
|  | The drug is exempt from IND requirements. (Complete Section 5) | |
| **3 - IND Validation** (MUST check at least one) | | |
|  | Protocol includes written communication from the sponsor documenting the IND number. | |
|  | Sponsor protocol is imprinted with the IND number. | |
|  | Protocol includes written communication from the FDA documenting the IND number.  *Note: This is required if the investigator holds the IND. Also see section #6.* | |
| **4 – Drug Control** | | |
|  | Protocol outlines the plan for storage, control and dispensing of the drug and the plan is adequate to ensure only authorized personnel will use the drug in study participants. A dispensing log should be kept. | |
| **5 - IND Exceptions**  *Note: All criteria for one category must be checked for the category to be met. If no categories are met, then the drug is not exempt from an IND.* | | |
|  | **Category #1: Approved Drug (21 CFR 312.2 (B)(1))** | |
|  | The drug is lawfully marketed in the United States. |
|  | The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug. |
|  | The research is not intended to support a significant change in the advertising for the drug. |
|  | The research does not involve any of the following that significantly increases the risk (or decreases the acceptability of the risks) associated with use of the drug:  A route of administration;  Dosage level;  Use in a patient population;  Other factor. |
|  | The research is conducted in compliance with the marketing limitation described in 21 CFR 312.7. |
| **Category #2: Serological Test (21 CFR 312.2 (b)(2))** | |
|  | The research involves a clinical investigation for an in vitro diagnostic[[4]](#endnote-4) biological product that involves one or more of the following:   * Blood grouping Serum * Reagent red blood cells * Anti-human globulin |
|  | The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure. |
|  | The method of shipping the diagnostic test complies with 21CFR 312.160. |
| **Category #3: Placebos (21 CFR 312.2 (b)(5))** | |
|  | The research includes a clinical investigation involving the use of a placebo when the investigation does not otherwise require the submission of an IND. |
| **Category #4: Bioavailability/Bioequivalence Studies (21 CFR 320.31 (b) and (d))** | |
|  | The active moiety of the drug product is identical to that in an FDA drug. |
|  | The drug product is not radioactively labeled. |
|  | The drug is not cytotoxic. |
|  | The dose (single or daily) does not exceed the dose in the labeling of the approved version of the drug product. |
|  | The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31 (d)(1). |
| **Category #5: Radioactive Drugs for Research Use (21 CFR 321.1)** | |
|  | The drug has been approved by the Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria established in 21 CFR 321.1 (b). |
| **Category #6: Cold Isotopes for Research Use (FDA Enforcement Discretion)** | |
|  | The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry. |
|  | The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject. |
|  | The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies. |
|  | The quality of the cold isotope meets relevant quality standard. |
| **6 – Oversight for Investigators who hold the IND** | | |
|  | Investigators are meeting [additional FDA requirements](https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/additional_criteria_checklist_sponsor_investigator_responsibilities.docx) when taking on the role of sponsor investigator (holding an IND). | |

1. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to the FDA meet this requirement. [↑](#endnote-ref-1)
2. The term “drug” means the following:

   Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

   Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

   Articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

   Articles intended for use as a component of any article specified in clause (A), (B), or (C). [↑](#endnote-ref-2)
3. This refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of a patient. If the protocol specified the use of the drug, it is not in the course of medical practice unless the use of the drug is entirely up to the discretion of the practitioner. [↑](#endnote-ref-3)
4. In vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are devices as defined in section 201(h) of the Public Health Service Act and may also be biological products subject to section 351 of the Act. [↑](#endnote-ref-4)